DEC 1 2 2003

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K032952

(1) **Contact Person:** Barbara DeBiase, Director, Sienco Inc.
Summary Preparation Date: 26 November, 2003

(2) **Device Trade Name:** aiACT Kit
Common Name: Activated Clotting Time (ACT) Test
Classification Name: Activated Whole Blood Clotting Time Test
Classification: Class II, 21 CFR 864.7174

(3) **Identification of predicate device to which substantial equivalence is being claimed:** SonACT Kit, included in 510(k) # K952560

(4) **and (5) Device Description and Intended Use:**

The aiACT Kit is an in vitro diagnostic test for use with the Sonoclot® Coagulation & Platelet Function Analyzer System. The aiACT test is an activated whole blood clotting time test which uses a blend of celite and clay for contact activation. It may also be used with citrated whole blood.

The aiACT Kit is intended only for high dose heparin anticoagulation management (ACT ≥ 400 seconds on Sonoclot Analyzer) as typically encountered during cardiopulmonary bypass surgery. The aiACT test provides ACT results that are substantially unaffected by aprotinin. When used with the Sonoclot Analyzer System, the aiACT test provides quantitative Onset/ACT and Clot Rate results. **Do not use the aiACT test for platelet function assessment.**

(6) Technological Characteristic Comparison of the aiACT+ Kit to the standard SonACT Kit:

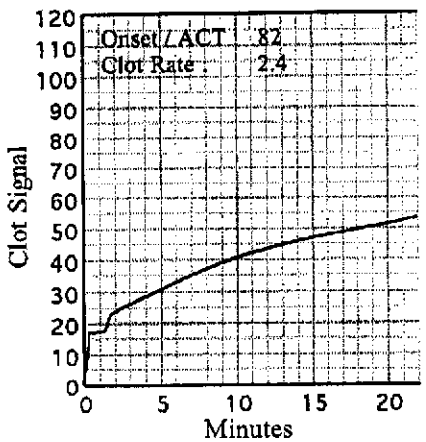
ITEM	aiACT	STANDARD SONACT
Classification Name	Activated Whole Blood Clotting Time Test	Activated Whole Blood Clotting Time Test
IVD Reagent for Use With	Sonoclot Coagulation & Platelet Function Analyzer	Sonoclot Coagulation & Platelet Function Analyzer
Intended Use	High dose heparin anticoagulation management , especially in the presence of aprotinin	General purpose global hemostasis monitoring, hypercoagulable and hyperfibrinolysis screening, platelet function assessment, anticoagulation management (low to high heparin levels)
Results Provided	Quantitative results for Activated Clotting Time (Sonoclot Onset Time) and rate of fibrin polymerization (Sonoclot Clot Rate).	Quantitative results for Activated Clotting Time (Sonoclot Onset Time) and rate of fibrin polymerization (Sonoclot Clot Rate). Qualitative and quantitative platelet function information (time to peak, clot retraction).
Test Design	Yellow plastic lidded cuvette containing contact activator and magnetic stir bar	Colorless plastic lidded cuvette containing contact activator and magnetic stir bar
Kit Contents	Cuvettes, probes and instructions for use	Cuvettes, probes and instructions for use
Quality Control	Reference plasma quality control	Reference plasma quality control

(7) **Performance Comparison of the aiACT Kit to the standard SonACT Kit:** Expected values for the aiACT Kit and the standard SonACT Kit are provided in the tables below.

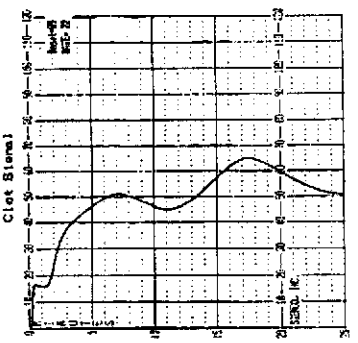
aiACT Test (#800-0442, #800-0441) Native Whole Blood - Normal Population, No Heparin	
Result	**Normal Range**
ACT/Onset	62-93 seconds
Clot RATE	22-41 Clot Signal Units / minute

Standard SonACT Test (#800-0435, #800-0434) Native Whole Blood - Normal Population, No	
Result	**Normal Range**
ACT/Onset	85-145 seconds
Clot RATE	15-45 Clot Signal Units / minute
Time to Peak	< 30 minutes

Normal, aiACT Test, Native Whole



Normal, SonACT Test, Native Whole Blood



Onset/ACT: 89
Clot RATE: 22
Time to Peak: 17.5

Nov 29, 2003

Jon Henderson, President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Barbara DeBiase
Director
Sienco, Inc.
11485-A West 48th Avenue
Wheat Ridge, Colorado 80033

DEC 12 2003

Re: k032952
Trade/Device Name: aiACT Kit
Regulation Number: 21 CFR § 864.7140
Regulation Name: Activated Whole Blood Clotting Time Test
Regulatory Class: II
Product Code: JBP
Dated: September 16, 2003
Received: September 22, 2003

Dear Ms. DeBiase:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032952

Device Name: aiACT Kit

Indications For Use:

The aiACT Kit is an in vitro diagnostic test for use with the Sonoclot® Coagulation & Platelet Function Analyzer System. The aiACT test is an activated whole blood clotting time test which uses a blend of celite and clay for contact activation. It may also be used with citrated whole blood.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional Format 3-10-98)

510(k) K032952

Prescription Use ✓